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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,744	01/27/2004	David Halpern	2100280-991102	2838

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EXAMINER

LACYK, JOHN P

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/766,744

Applicant(s)

HALPERN ET AL.

Examiner

John P Lacyk

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Maruyama et al., in the article "Work in Progress: 252Cf Neutron Brachytherapy for Hemispheric Malignant Glioma" .

Maruyama et al teach the treatment of glioblastoma with 252-Cf neutron brachytherapy in the Materials and Methods section, pages 171-172. Further, they teach the debulking of the tumor in line 4 of the Tumor evaluation and entry section of the Materials and Methods section of page 171. The tumor is in the brain, as it is a glioblastoma. As "miniaturized" is such a broad term, the Examiner holds it inherent that any sources would be made as small as necessary for the method.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 13-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al article as applied to claims 1-12 above, in view of Wierzbicki et al article, "Measurement of augmentation of 252 Cf implant by 10 B and 157 Gd neutron capture".

Maruyama et al fail to teach the use of neutron capture therapy, NCT. Wiezbicki et al teach the use of ^{10}B and ^{157}Gd neutron capture therapy, specifically in paragraphs 3-4 of column 1 of page 788. The same section states that the compound is ideally delivered to the area by tumor-specific pharmacologic or biological carriers. It would have been obvious to one of ordinary skill in the art, to add NCT to ^{252}Cf neutron brachytherapy to increase its effectiveness, as taught by Wiezbicki et al, in the conclusions section of page 790.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maruyama et al article as applied to claims 1 and 7 above, and further in view of Barthelemy et al article, "The Development of Californium-252 Sealed Sources at the Commissariat A L'Energie Atomique".

Maruyama et al teach all the limitations of claim 18 except for the exact size of the source. In Figure 13 of page 212, Barthelemy et al teach that the capsule of the source has an outside diameter of .70 mm and a length of 4 mm. Further, Barthelemy et al teach that the source is nominally 32 ug. However, there are other sources, as shown in Table III of page 207, which contain 100-500 ug of ^{252}Cf . It would have been an obvious matter of design choice to make the different portions of the capsule and source of the combination of Maruyama et al whatever relative sizes were desired, such as taught by Barthelemy et al, since such a modification would have involved a mere change in the proportions of components. A change in proportion is generally

Art Unit: 3736

recognized as being within the level of ordinary skill in the art. *In re Reese*, 129 USPQ 402.

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No.

6,319,189. Although the conflicting claims are not identical, they are not patentably distinct from each other because the elimination of the catheter and remote afterloader used to insert the neutron source is an obvious expedient since it is well known in the art to use a catheter and afterloader to insert radioactive sources into the body for treatment.

8. Claims 1-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No.

6,685,619. Although the conflicting claims are not identical, they are not patentably


Art Unit: 3736

distinct from each other because the elimination of the catheter is an obvious expedient since it is well known in the art to use a catheter to insert radioactive sources into the body for treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P Lacyk whose telephone number is 703-308-2995.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



John P Lacyk
Primary Examiner
Art Unit 3736

J.P. Lacyk